Michael L. Goodis, P.E.
Director, Registration Division
Office of Pesticide Programs
Mail Code 7505P

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Thomas Marvin.

Bayer U.S.
Monsanto Company
Crop Science
Regulatory Affairs

801 Pennsylvania Ave, NW
Suite 745
Washington, DC, 20004
United States

Tel. +1 202 383 2851
thomas.marvin@bayer.com

www.bayer.com

Subject: M1768 Herbicide / XtendiMax® With VaporGrip® Technology, EPA Reg. No. 524-617; Submission of data in response to EPA's letter regarding FIFRA § 6(a)(2)

Dear Mr. Goodis:

We write in response to your letter of March 27, 2020 to multiple dicamba registrants, including Bayer Crop Science,[1] regarding FIFRA § 6(a)(2) and its implementing regulations. Your letter refers to dicamba registrants' general obligations under § 6(a)(2) and also to two specific topics: (1) dicamba research and field trials by academic scientists; and (2) lawsuits related to dicamba registrants' products. As described in detail below, academic research overwhelmingly supports the conclusions EPA has previously reached regarding Monsanto's low-volatility dicamba product XtendiMax® Herbicide with VaporGrip® Technology (XtendiMax). The pending lawsuits (and recent related press stories reciting a range of 2015–16 allegations) do not undercut those scientific conclusions. We describe all of this information at length herein and then further respond to each of EPA's specific requests for additional information, outlining the additional materials we are submitting in conjunction with this response. *See infra* pp. 13–18. Specifically, we:

- Describe the extensive body of scientific information supplied to EPA since 2015 regarding Monsanto's XtendiMax, including a large number of

[1] The Bayer Group has acquired Monsanto Company, the registrant. Bayer brand is now the corporate brand for the combined company; however, the legal entity Monsanto Company continues to operate with the same name and remains responsible for maintaining compliance with all relevant statutory, regulatory, and permit requirements.

confirmatory research studies and field trials conducted in 2017, 2018, and 2019 by independent academic scientists in locations across the U.S.;

- Describe the steps taken by Monsanto to investigate specific allegations of dicamba movement and provide results previously reported to EPA from those investigative efforts, additional detail on those investigations where available, and data demonstrating significant growth since 2010 in the use of other generic forms of dicamba (on corn and other crops) to address glyphosate-resistant weed biotypes;

- Describe the *Bader Farms* litigation, *Bader Farms Inc. v. Monsanto Co.*, No. 1:16-cv-299 (E.D. Mo. filed Dec. 30, 2016) and supply a substantial volume of record material from that litigation, including full trial transcripts and exhibits, a detailed explanation of the specific allegations in the case, and the parties' expert reports in the case; and

- Explain ongoing proceedings in the dicamba Multi-District Litigation (MDL), *In re: Dicamba Herbicides Litigation*, No. 1:18-md-2820 (E.D. Mo. filed Feb. 1, 2018), including orders on expert testimony entered by the presiding judge (*i.e. Daubert* rulings).

We wish to ensure that the agency has the necessary information on each of these identified topics. While we are confident that Monsanto has met its obligations under FIFRA § 6(a)(2),[2] we urge you to raise any specific concerns you may have about what has been provided to date, so we can be certain there is absolutely no misunderstanding.[3] Please let us know as soon as practicable when we can follow up with you on this letter and address any additional questions you may have.

Finally, as you know, a large percentage of our nation's 2020 soybean and cotton crops will again be dicamba-tolerant. We have seen very healthy yields of both crops in recent years. Successful yields in 2020 and the future in many parts of the U.S. will require continued successful control of glyphosate-resistant weeds, and thus appropriate applications of XtendiMax or other dicamba herbicides. We are committed to working with EPA to ensure that this success continues.

Background

EPA initially approved the registration for XtendiMax (EPA Reg. No. 524-617) on November 9, 2016, and then again on November 1, 2018, for use on dicamba-tolerant soybeans and cotton. These registrations were based on a range of scientific submissions provided to the agency over several years, including dozens of scientific studies and field trials conducted by Monsanto and academic

[2] The material submitted with this response is intended to provide EPA additional information beyond data the registrant was required to submit pursuant to § 6(a)(2). Monsanto's submission of litigation-related allegations and claims is not intended to suggest that any of the allegations or claims are factual or accurate. As indicated in the litigation pleadings, Monsanto Company disputes and has denied almost all of the principal allegations in those cases.

[3] Further, to ensure clarity, we also note that certain of our past § 6(a)(2) submissions were temporarily misplaced by the agency. Our May 25, 2018 letter to Brian Dyer at EPA outlined how the designated EPA recipient was on leave and the agency did not realize until May 2018 that it had received certain 2017–18 Monsanto § 6(a)(2) submissions. We would be pleased to walk through those past submissions with you again to ensure the agency has accounted for all relevant information.

scientists assessing the potential for spray drift and volatility. As EPA explained in its 2018 registration decision, evidence from these studies, in conjunction with EPA's highly restrictive XtendiMax label requirements, all confirm EPA's conclusion that the XtendiMax registration will not cause unreasonable adverse effects on the environment.

In addition to all of the information submitted prior to the most recent registration, studies from Monsanto and academic scientists *since* the 2018 registration add substantial confirmatory evidence to that conclusion. To date, numerous field studies of XtendiMax off-target movement have been conducted by Monsanto and academic scientists over a broad range of geographies, temperatures, humidity, soil types, crop growth stages, field sizes, and environmental conditions that are highly representative of farming conditions where cotton and soybeans are grown in the United States. The results from these field studies make clear that use of the low-volatility XtendiMax dicamba formulation according to label instructions is protective of non-target plants and any threatened or endangered species.

Building on the successes of the low-volatility XtendiMax formulation, Monsanto's latest innovation in this area is the development of VaporGrip X[4] as a standalone adjuvant to be added to XtendiMax as a tank-mix partner. VaporGrip X will even further reduce the very low potential for volatility and supplies yet further confidence in the post-emergent applications of dicamba. The five 2019 studies by Monsanto and independent academic scientists testing applications of XtendiMax with VaporGrip X demonstrates that the tank mix further reduces volatile mass loss by greater than 60% beyond the already low-volatility XtendiMax formulation.

A. Field Studies

Over more than six years, Monsanto and academic scientists have conducted numerous field studies of XtendiMax off-target movement over a broad range of typical cotton and soybean growing conditions. Each of these studies has been provided to EPA, either by Monsanto directly or at Monsanto's request or suggestion. Certain of these studies pre-dated EPA's 2016 registration of post-emergent dicamba applications, but a large majority of the confirmatory studies have been conducted *since* 2016. Collectively, these studies overwhelmingly reinforce EPA's conclusions that spray and vapor drift will not occur beyond the label's required buffer distances at levels that would cause any impacts.

i. 2015 and 2016 Studies

In 2015 and 2016, Monsanto conducted six dicamba volatility field studies in Georgia and Texas—two using XtendiMax, two using Roundup Xtend, and two using Clarity (M1691). As part of the registration process for XtendiMax, EPA performed an independent assessment of four of those studies. The Georgia study conditions included a soil pH of 5.6 and peak surface soil and air temperatures of 117 °F and 89 °F, respectively, while the Texas study was conducted on soil with a

[4] VaporGrip X is Bayer's current internal project name for utilizing additional VaporGrip in tank mixes as a volatility-reducing adjuvant.

pH of 6.0 and peak surface soil and air temperatures of 155 °F and 95 °F, respectively. EPA noted that these conditions "made for near-idealized conditions for volatilization occurring after applications," approaching the worst-case scenario for maximizing dicamba's volatility, and concluded that based on the results of these studies, vapor drift occurring due to volatilization appeared unlikely to be a concern for impacts off the treated field.[5]

ii. 2017, 2018, and 2019 Studies

Monsanto conducted seven additional field volatility studies in 2017[6] and 2018 in Arizona, Illinois, Minnesota, Missouri, Nebraska, North Dakota, and Australia. These studies tested the volatility potential of the common tank mix of XtendiMax and Roundup PowerMax (glyphosate) in a broader range of spray-area size, environmental conditions, and geographic locations. The results of these studies were consistent with the previous studies EPA had considered for XtendiMax's initial registration and confirmed EPA's conclusions that dicamba volatility did not represent a threat to off-target species when used according to label requirements.[7]

Also during 2017 and 2018, a number of independent academic scientists conducted studies in multiple states evaluating the off-target movement potential of XtendiMax under typical agronomic conditions. The body of data from these studies is mostly uniform and reinforces the results of Monsanto's field studies. The studies occurred in every cotton- and soybean-growing region in the United States on both small and very large acreage plots. Soybeans not tolerant to dicamba are known to be highly sensitive to the product, so the studies were designed to evaluate the extent to which potential impacts on soybeans, including visual symptomology, could be seen at various distances from XtendiMax applications. Almost all the 2017–18 studies provided consistent results. For example, studies by Werle in Wisconsin (7/11/2018), Young in Indiana (8/27/2017 and 8/9/2018), Sprague in Michigan (6/12/2018), Kruger in Nebraska (7/10/2018), and Steckel in Tennessee (7/27/17) reached the same fundamental conclusion as Monsanto's studies: XtendiMax applications were not producing material indications of visual symptomology beyond the field.

Indeed, although EPA focused primarily upon a threshold of 20% visual symptomology in its evaluation of the potential for off-target movement (and explained that such measurements can be

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[5] U.S. EPA, *M-1691 Herbicide, EPA Reg. No. 524-582 (Active Ingredient: Dicamba Diglycolamine Salt) and M-1768 herbicide (Xtendimax), EPA Reg. No. 524-617 (AI: Diglycolamine Salt with VaporGrip™) – Review of EFED Actions and Recent Data Submissions Associated with Spray and Vapor Drift of the Proposed Section 3 New Uses on Dicamba-Tolerant Soybean and Cotton*, 6 (Nov. 3, 2016) ("*M-1768 Review of EFED Actions*").

[6] The methodology and results from the 2015, 2016, and 2017 studies have been accepted for publication in the Journal of Agricultural and Food Chemistry (https://doi.org/10.1021/acs.jafc.9b06451 and https://doi.org/10.1021/acs.jafc.9b06452).

[7] These studies are reviewed at greater length in Monsanto's August 3, 2018 and February 28, 2020 papers. *See generally The Scientific Basis for Understanding the Off-Target Movement Potential of XtendiMax* (MRID 50642701) (Aug. 3, 2018) ("*2018 White Paper*"); *Summary of Studies Conducted or Supported by Monsanto to Support Re-Registration of M1768* (MRID 51038601) (Feb. 28, 2020) ("*2020 White Paper*").

subjective[8]), even materially lesser symptomology (10% or less) was only observed well within the XtendiMax label downwind-buffer distance of 33 meters. For example, the maximum distances to 10% symptomology in the above studies were: less than 10 meters (Young 2017), less than 15 meters (Kruger), 17 meters (Werle), 18 meters (Steckel, measured as average distance), 20 meters (Young 2018), and 25 meters (Sprague). Moreover, EPA specifically obtained data on plant height reduction from certain of these academic studies: the Young, Sprague, and Kruger studies found that the 5% plant height reduction measurements (EPA's plant effect endpoint) were consistent with and aligned to those studies' observations of visual symptomology.[9] Additionally, several of these academic scientists also utilized equipment to collect deposition data reflecting the volume of dicamba present in the air that subsequently settled on the detection equipment. This data showed results consistent with each other and with Monsanto's own studies: a low level of dicamba detected at relevant distances consistent with the confirmatory visual symptomology observations and 5% plant height reduction data.[10] Collectively, this body of consistent results in multiple trials, alongside Monsanto's consistent results, is more than sufficient to give EPA confidence that the approved post-emergence dicamba uses will not cause unreasonable adverse effects on the environment.[11]

Indeed, multiple studies conducted in 2019 also reinforce that same conclusion. Studies by Li in Alabama (8/6/2019), Culpepper in Georgia (9/10/2019), Smeda in Missouri (7/23/2019), Kruger in Nebraska (8/18/2019), and Werle in Wisconsin (7/14/2019) again examined the off-target movement potential of an XtendiMax and Roundup tank mix, with the inclusion of VaporGrip X as an adjuvant. In addition to geographical diversity, these studies captured a range of spray conditions, including varying application areas, air temperatures, crop heights, and relative humidity. The maximum distance to 20% visual symptomology was: 3 meters (Kruger), 7 meters (Smeda), and 11 meters (Werle). The maximum distance to 10% visual symptomology was: 5 meters (Kruger), 16 meters (Smeda), and 21 meters (Werle).[12] The 2019 academic studies' measurements of off-field dicamba air concentrations were also consistent with these observations and well within EPA's risk assessment.[13]

As a condition of EPA's reregistration of XtendiMax, Monsanto also conducted three additional field studies in 2019 to provide EPA with additional confirmation of the findings of previous studies. These Illinois, Mississippi, and Missouri studies measured dicamba levels outside

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[8] *See* U.S. EPA, *Summary of New Information and Analysis of Dicamba Use on Dicamba-Tolerant (DT) Cotton and Soybean Including Updated Effects Determinations for Federally Listed Threatened and Endangered Species*, 49, 79 (Oct. 31, 2018) ("*2018 EFED Update*").

[9] *Id.* at 87.

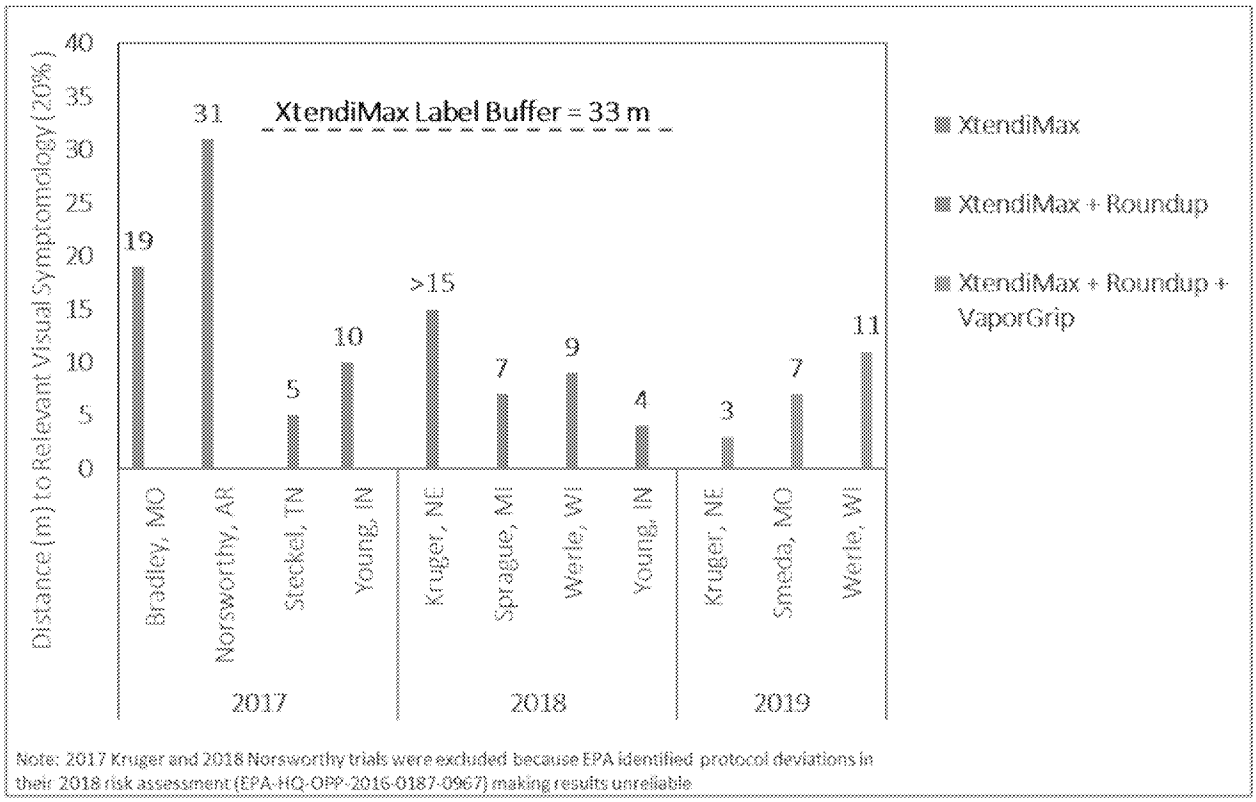
[10] The results from the 2018 academic studies have been accepted for publication in Weed Technology (https://doi.org/10.1017/wet.2020.17).

[11] Although Bradley's 2017 study in Missouri indicated 20% visual symptomology at somewhat further distances than the other studies, his results (19 meters) were still within the 33 meter downwind buffer. *See 2018 EFED Update*, 86. Bradley's 2017 study did not provide plant height data. *See id.* Another study conducted by Kruger in 2017 was reportedly confounded by a nearby application of dicamba during the study and so is not discussed here. *See 2018 EFED Update*, 86–87.

[12] The results of these studies are discussed in Monsanto's February 28, 2020 paper. *See generally 2020 White Paper.*

[13] *See 2020 White Paper*, 28.

the treated field and included an assessment of plant effects on dicamba-sensitive soybeans. As with the previous studies, they all confirmed EPA's conclusions as to dicamba volatility. No-effect distances to plant height reduction were 0 meters in non-downwind directions. Findings regarding primary drift were also consistent with previous studies.[14]



For completeness, we also include here a description of Arkansas research, of which EPA is already aware. In 2017 (as is evident from the chart above), that researcher reported maximum 20% visual symptomology measurements out to 31 meters. But that same Arkansas study observed maximum 5% plant height reduction measurements at a much shorter distance—*less than 3 meters.*[15] There was no effort to explain those two differing sets of observations.

In 2018, that Arkansas researcher conducted another study on a soybean field during the R1/R2 growth phase (when EPA's label does not allow spraying)—a problematic study timing because, as EPA noted in the 2018 EFED Update, plant height measurements are unreliable in this reproductive stage. As EPA concluded, that study did not follow the testing protocol that the academics had collectively established and reached results that were inconsistent with the other studies' conclusions.[16] EPA inquired of the researcher "why his results were different than those in

[14] *See 2020 White Paper*, 27.
[15] *2018 EFED Update*, 86.
[16] *Id.* at 25, 86–87, 133.

other areas of the country?" The researcher responded: "he wasn't sure."[17] Moreover, once that researcher's quantitative measures of off-target movement, such as dicamba flux and deposition data, ultimately became available in 2019, it became evident that the Arkansas data recording levels of airborne dicamba were consistent with many other academic scientists' studies (and with Monsanto studies) that simultaneously found ***far smaller distances*** to visual symptomology and 5% plant height reduction.[18] As indicated, EPA concluded that the 2018 Arkansas study did not produce reliable plant height measurements.[19] In its 2018 registration decision, EPA explained: "The use of plant height data [from multiple other studies] eliminates the uncertainty associated with the subjective nature of VSI measurements."[20]

iii. Additional Confirmatory Analyses and Information

To address inquiries received from the field about potential dicamba drift, Monsanto engaged in a range of additional analyses. To put these issues in context, it is important to understand more fully the growing use of dicamba applications occurring to address glyphosate-tolerant weeds in other crops and other agricultural and non-agricultural land. These are uses other than over dicamba-tolerant crops, such as on corn, small grains, or pastureland, and are referred to here as "generic" dicamba use for these conventional applications. These generic dicamba formulations are not specially formulated for low volatility (as XtendiMax is) and are not subject to the highly restrictive and specialized off-target movement-reduction measures mandated by the XtendiMax label.

As was illustrated in Monsanto's August 3, 2018 paper, sales of generic dicamba increased significantly between 2010 and 2017, roughly doubling by 2017 (see figure below).[21] As illustrated, generic dicamba accounted for nearly half the total dicamba volume applied in 2017.[22] The same trends of increased generic dicamba use continued in 2018 and 2019.[23]

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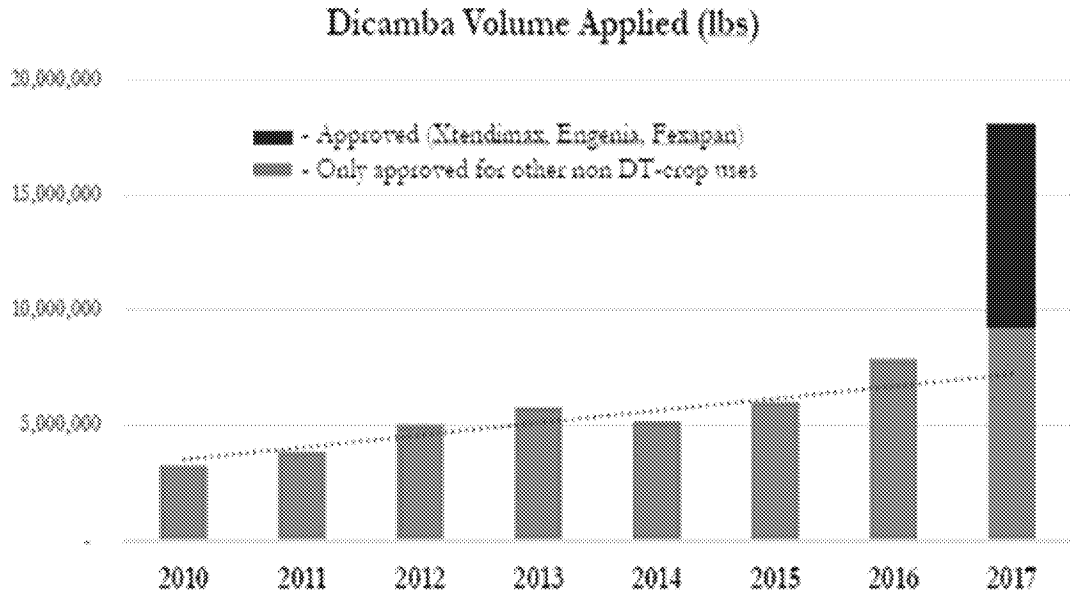
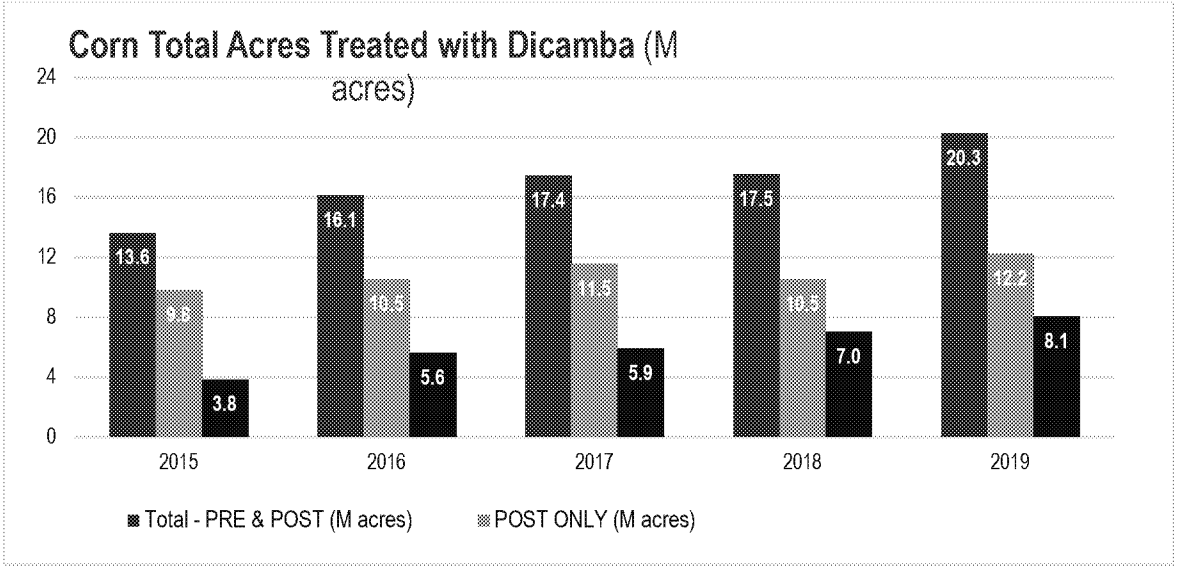
[17] *Id.* at 133.
[18] Soltani et al., 2020 (https://doi.org/10.1017/wet.2020.17).
[19] *Id.* at 86.
[20] *Id.* at 64.
[21] *See 2018 White Paper*, 35.
[22] *See id.*
[23] Data obtained from AgroTrak® (and licensed via Kynetec) demonstrates that the volume of dicamba only approved for non DT-crop uses increased to approximately 9.9 million pounds in 2018 and 11.6 million pounds in 2019.

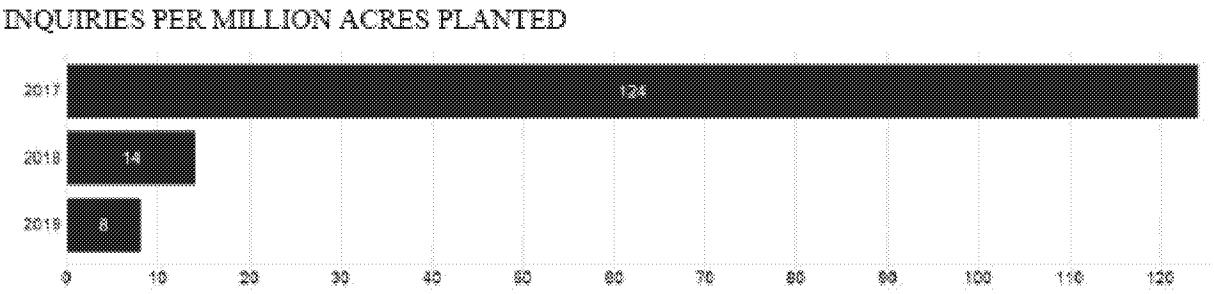


Indeed, data shows significant growth in use of generic dicamba on corn.



As previously reported to EPA, Monsanto has conducted many specialized reviews of inquiries about complaints of off-target dicamba movement since 2017, including by conducting *on-*

site field inspections.[24] Following the 2017 and 2018 seasons, Monsanto worked with EPA to refine the XtendiMax label with the specific purpose of strengthening label restrictions and reducing misuse of the product. Since 2017, off-target dicamba movement inquiries received by Monsanto have dropped *significantly*, even though the number of soybean acres planted have increased substantially during that period.[25]



In addition to the drop in the total number of dicamba off-target movement inquiries, the geographic focus of the inquiries has also shifted. In 2017, for example, a large percentage of the inquiries were from Arkansas (where Engenia but not XtendiMax was applied) and Missouri. Since the changes in labeling for both Engenia and XtendiMax, the *number of inquiries in those areas has fallen dramatically*. As Monsanto has previously reported to EPA, we have conducted dozens of on-site reviews of inquiries in each of the relevant geographic areas. In 2019, 86% of fields exhibiting uniform dicamba symptomology had at least one corn field within 150 feet of the inquiry field, and 75% of inquiry fields had two or more corn fields within 150 feet of the inquiry field.[26] Information we reported to EPA in the 2018 White Paper demonstrated similar findings with respect to proximity of corn fields to inquiry fields.[27]

Indeed, this observation is not surprising given the rise in recent years of generic dicamba use over corn, as described above. Moreover, it appears that the impact of generic dicamba applications over corn may have been heightened this year in multiple states because weather delayed those corn applications so that they had more potential to impact neighboring soybean fields.[28] Again, those generic dicamba applications over corn are not formulated as low-volatility dicamba products, and are not labeled with the same mandatory drift-reduction measures applicable to XtendiMax.

The specific 2019 data from Monsanto's inquiry reviews is also instructive. Although other factors included use of non-approved tank mix partners, poor tank and spray system hygiene, and other circumstances where applicators have not fully complied with the label, 2019 data demonstrated that incidents of applicator-reported failures to follow specific application requirements decreased

[24] As a condition of the 2018 registration, Monsanto has provided enhanced incident reporting information to EPA on a monthly basis since March 2019.
[25] *2020 White Paper*, 44.
[26] *2020 White Paper*, 49.
[27] *2018 White Paper,* 38.
[28] *2020 White Paper,* 49.

from 2018 to 2019.[29] For more detail on these inquiry reviews, please see Monsanto's 2020 White Paper and the additional detailed information summarized below.

Finally, it is important to reiterate that observations of potential symptomology are not actually indicative that a field may experience any yield loss; indeed, the yield data analysis Monsanto supplied in its 2018 White Paper demonstrated a *positive correlation* between the counties with the highest number of drift "complaints" in 2017 and increase in overall yield (*i.e.* the counties with the highest number of complaints also experienced record or very significant soybean yields). In Arkansas, for example, data demonstrated that every one of the counties with the highest number of 2017 symptomology "complaints" experienced significant improvements in yield per acre.[30] Similar correlations were demonstrated for relevant portions of Missouri, Tennessee, and Illinois.[31] All of these findings are consistent with soybean yield data compiled by the U.S. Department of Agriculture, which reveals that soybean yields since 2017 continue to remain steady or increase even as growers continue to battle glyphosate-tolerant weeds.[32]

B. Litigation

In prior § 6(a)(2) submissions, Monsanto has identified for EPA all of the pending litigation matters alleging injury from alleged dicamba off-target movement. With this submission, we provide a significant volume of additional material, specifically including full trial transcripts, trial exhibits, expert reports, and relevant deposition transcripts. *See infra* pp. 14–17. In order to understand that material, it is important to understand what the pending litigation matters address and the current posture of those cases.

Only one case to date has been tried to a verdict: *Bader Farms, Inc. v. Monsanto Co.*[33] *Bader Farms* was initially filed in November 2016 in Dunklin County, Missouri. The initial Complaint did not relate to XtendiMax, which had not even been introduced to the market yet, but instead to allegations that Monsanto had marketed dicamba-tolerant seed in 2015–16 *before* XtendiMax was approved.

The original allegations were that Monsanto willfully and negligently released Xtend seeds "without an accompanying EPA-approved dicamba herbicide," leaving famers who grew Xtend crops "with the unenviable choice of either allowing their Xtend crops to be destroyed by weed overgrowth or to use the only dicamba that is currently on the market—old dicamba [*i.e.* generic dicamba]—to spray on their Xtend crops."[34] The plaintiff alleged that growers would recognize that they could illegally apply generic dicamba (without any of the off-target movement-reduction qualities of XtendiMax) to kill glyphosate-resistant weeds over fields planted with Xtend dicamba-resistant seeds. As a consequence, Bader Farms argued, the sale of Xtend seeds indirectly "caused" the Bader Farms

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[29] *2020 White Paper*, 47–48.
[30] *2018 White Paper*, 28–29.
[31] *Id.* at 28–30.
[32] *2018 White Paper*, 26–31, *2020 White Paper,* 41–43.
[33] No. 1:16-cv-299 (E.D. Mo. filed Dec. 30, 2016).
[34] *Bader Farms* Complaint, ¶ 11, 25.

peach orchards to be impacted by drift from growers who illegally applied those generic dicamba products, thus impacting peach yield.

In subsequent years, after XtendiMax was approved (in late 2016), Bader Farms' complaint was amended to add other allegations that XtendiMax applications have also moved off target and impacted the orchards. However, the only test that ever detected any dicamba residue on the Bader Farms' peach orchards was conducted *before* XtendiMax was approved by EPA. The evidence from trial indicated that aerial burn-down applications of generic dicamba to a cornfield were responsible for that one positive test for dicamba residue.[35] Tests for residue in subsequent years detected no such dicamba residue on the orchard.[36]

At trial, Bader Farms did not present any evidence that any known XtendiMax application drifted to the orchard. Instead, Bader Farms' expert alleged that, because Xtend seeds were purchased by growers with addresses in the neighboring areas, growers must have planted it nearby, used some formulation of dicamba—approved or unapproved—over the top of crops, done so in a way that led to off-target movement, and that Monsanto was therefore liable.[37] Plaintiff's expert, Dr. Ford Baldwin, acknowledged that he did not have information about any specific dicamba applications in the vicinity, but relied instead on the "seed sales information in a 15-mile radius."[38] The same expert acknowledged that he did "not have any evidence of where any of those seeds were actually planted," much less any spray records or other evidence of any dicamba applications.[39]

Given that there was no evidence of *any* specific dicamba application at all that moved off target to the Bader Farms peach orchards, Plaintiff did not attempt to show any off-target movement from an XtendiMax application in particular. There was no expert testimony about any particular incident or occasion when XtendiMax caused an observed impact off-target. Nor was there evidence of any other alleged XtendiMax impact on any crop in any other neighboring farm. (Indeed, as noted, total soybean yield in the Missouri county at issue hit record highs in 2017 and has been very healthy since that time. *See supra* p. 9.) Indeed, the judge did not require the jury to make any finding that XtendiMax was involved in any application at issue or that XtendiMax had ever moved off target to reach the Bader Farms peach orchards. Rather, the jury was allowed to assume that dicamba must have been the cause based on the fact that it was sold to purchasers with addresses in the neighboring area, regardless of whether or not that dicamba was XtendiMax. The judge indicated that he "didn't understand that the—that the plaintiffs' claim was predicated on XtendiMax alone but on all dicamba herbicides"; "we are not talking about specific products that have to be identified anymore. It's any dicamba that would have been sprayed over the top. It's not limited to XtendiMax or Engenia."[40]

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[35] *Bader Farms* Trial Tr. 1045:16–1046:1.
[36] *Id.* at 1085:1–21.
[37] *Id.* at 1298:18–1299:3, 1403:5–1404:4.
[38] *Id.* at 1298:18–1299:3.
[39] *Id.* at 1403:5–1404:12.
[40] *Id. See also id.* at 2294–2295:3

In addition to there being no evidence that XtendiMax ever reached the Bader Farms orchards in any way, there was substantial evidence that the orchard suffered a different type of damage entirely. Monsanto's experts testified at length about an endemic peach disease in the specific area at issue called armillaria root rot that had historically devastated other orchards and was responsible for the yield impacts Bader Farms alleged. A prominent weed scientist whose expertise is in peaches testified based on six visits that Bader Farms' peach trees did not have any symptomology of dicamba exposure, much less symptomology that could be associated with yield loss.[41] Plaintiff's expert, Dr. Baldwin, admitted that armillaria root rot was present on Bader Farms,[42] a fact to which two plant pathologists with expertise in peach trees also attested and which was confirmed by genetic testing.[43] The plant pathologists were unequivocal that the armillaria root rot found in the peach orchards will kill peach trees, and eventually entire orchards, independent of any herbicide exposure.[44] They were also able to confirm based on aerial photographs that the armillaria root rot had been present on Bader Farms since long before the release of Xtend seed.[45] Plaintiff's expert did not refute this.[46] Instead, he testified that the armillaria root rot attacked Plaintiff's peach trees only because the trees were weakened as a result of dicamba exposure.[47] The plant pathologists, whose expertise is in pathogens like armillaria that attack peach trees, rejected this theory.[48] And again, the opinions of Plaintiff's experts were about dicamba generally, not XtendiMax specifically, and not about XtendiMax applied properly in accordance with EPA's label.

Press reports following the verdict focused on the most substantial portion of the damages award: the punitive damages component. As the court instructed, that component of the damages was focused *only* upon the alleged harm to the orchard in 2015–16 and Monsanto's conduct *before XtendiMax was approved.*[49] Thus, the focus of multiple press reports from the *Bader Farms* trial was about Monsanto conduct *before* the XtendiMax approval. Specifically, most of the press reports characterizing the testimony of Monsanto personnel address alleged conduct prior to December 2016. These allegations *predate* much of the XtendiMax-related testing described above, including specifically the many independent academic field trials from 2017–2019 which demonstrate that XtendiMax does not move beyond the mandatory buffer distance. *See supra* pp. 4–7.

Monsanto, along with co-defendant BASF Corporation, has filed post-trial motions with the court asking that the verdict be set aside in its entirety or that the punitive and compensatory damages

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[41] *Id.* at 1728:2–16.
[42] *Id.* at 1423:25–1424:2, 1454:21–23.
[43] *Id.* at 1885:7–1186:16, 2162:3–5.
[44] *Id.* at 1870:15–1871:21, 1888:1–1889:1, 2150:6–13.
[45] *Id.* at 1889:3–1897:6.
[46] *Id.* at 1426:2–15 (testifying that he had no opinion about what was causing the circular dead spots in Plaintiff's orchards that the pathologists testified was the result of armillaria years prior to the release of Xtend seed).
[47] *Id.* at 1424:9–19, 1454:13–16.
[48] *Id.* at 2151:7–9.
[49] *See id.* 2448:14–2449:8 (instructing jury on punitive damages, limited to years 2015 and 2016); *see also id.* at 2424:24–2425:1 (Plaintiff's counsel acknowledging that Plaintiff could not receive punitive damages for 2017 and 2018).

awards be reduced. Absent relief from the trial court, Monsanto anticipates appealing the *Bader* verdict to the United States Court of Appeals for the Eighth Circuit.

In addition to the *Bader Farms* case, thirty-five additional cases have been consolidated as part of a "multi-district litigation" (MDL) docket pending in the Eastern District of Missouri. None of those other cases has yet been set for trial or gone to trial. To date, the most significant ruling in that MDL is a ruling on the admissibility of expert testimony pursuant to the *Daubert* standard set by the United States Supreme Court.[50] In that ruling, Judge Limbaugh excluded virtually all of the opinions of Plaintiffs' three liability experts. In particular, the court noted that the experts had "never even visited soybean fields" in many of the states at issue, and that a field-by-field inspection is required because "on a case-by-case basis … multiple factors may impact and contribute to off-site movement of an herbicide."[51] Judge Limbaugh also noted that the opinions of Plaintiffs' experts on yield loss were equally unreliable, because exposure to off-target movement does not necessarily mean reduced yields. Indeed, the court noted that based on the results of Plaintiffs' own expert, "dicamba-exposed soybeans produced anywhere from a 13.5% yield **gain** to a 14.9% yield loss when compared to the average unexposed control."[52] As may be evident, Monsanto believes that had Judge Limbaugh's MDL *Daubert* ruling applied in similar fashion in *Bader*, it would have precluded the testimony of Bader's principal expert in that case—because he did not even visit the Bader orchards in 2015 or 2016, the principal years at issue.[53] Indeed, Monsanto believes that no dicamba off-target movement allegation can be assessed without a detailed review of the facts and circumstances at issue in that particular case.[54] That is consistent with Monsanto's review of dicamba off-target movement inquiries, addressed above, *see supra* pp. 7–9, and in Monsanto's multiple submissions to EPA, *see supra* n. 7 and *infra*.

Specific Additional Responses to EPA Information Requests

As noted above, Monsanto believes it has complied with FIFRA § 6(a)(2) and the terms of its registration but is nevertheless pleased to assist the agency with additional requests for information. In that spirit, in addition to the detailed explanations above, we supply the following further material in response to the specific numbered requests in the agency's March 27, 2020 letter.

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[50] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

[51] *In re: Dicamba Herbicides Litig.*, ECF #519.

[52] *Id.* at 10.

[53] *Bader Farms* Trial Tr. 1300:20–1301:6, 1428:11–16.

[54] As with the reports of off-target movement discussed above, investigations of the fields of various plaintiffs involved in the MDL have revealed alternative causes of alleged damage or no dicamba symptomology at all. For example, one plaintiff collected crop insurance for drought loss on the same fields he claims were damaged by dicamba, while another settled with an applicator for applying Engenia on a neighboring field but then turned around and sought compensation from Monsanto for alleged damage to the same field. Investigations of the fields of several other plaintiffs showed that off-target exposure had resulted from clear label violations, including violations of wind speed and buffer requirements; for example, one plaintiff was found by the Nebraska Department of Agriculture to have caused its own drift when it sprayed dicamba over its corn fields while the wind was blowing toward his non-dicamba tolerant soybean field.

1. Information regarding allegations of non-target plant damage from dicamba, including information on the location of alleged incidents, the distance between the damage location and any dicamba product applications to label-authorized or unauthorized sites, and any quantitative measurements of damage including visual injury, plant height, and plant yield.

To meet its general obligations under FIFRA § 6(a)(2) and its 2018 registration, Monsanto has submitted the following relating to allegations of off-target movement of dicamba:

- a poison control center report for a lawn and garden product containing dicamba and other active ingredients, submitted on July 11, 2017;
- a spreadsheet submitted directly to the Registration Division containing additional information for inquiries received by Monsanto directly from XtendiMax applicators through August 2017, submitted on or about August 30, 2017;
- an incident report of a possible human exposure, submitted on August 31, 2018;
- letters of February 5, May 30, August 30, and November 29, 2018 and January 31, 2019 submitting information pertaining to claims filed against Monsanto;
- quarterly reports beginning August 30, 2017 through February 28, 2019; and
- monthly reports beginning March 1, 2019 through April 25, 2020, per the terms and conditions of the 2018 registration.

In addition to what is required under FIFRA § 6(a)(2) and the 2018 registration's terms and conditions, Monsanto now offers an even more detailed summary of allegations previously disclosed to EPA to further assist the agency in its consideration of XtendiMax. The available information, which will be transmitted to EPA under separate cover via a secure file transfer website, is provided subject to the following notes:

- In addition to the requested categories of information, Monsanto has also provided further information, where available, about the off-target crop alleged to have been affected, the suspected route of off-target movement (equipment contamination, for example), and any known label violations.
- More specific location information is not available in cases where a report came from an applicator who did not identify an inquiry field, or where the report came from a non-applicator but the inquiry field was not visited. In the latter case, only the location of the caller is known, which may or not may be in close proximity to the allegedly impacted field.
- Information on the distance between the damage location and any potential applications that could contain dicamba is not available for the 2017 growing season and is only available for certain reports from the 2018 and 2019 growing seasons. Note that the

closest nearby field spraying dicamba may or may not have been the source field; for example, a soybean field could exhibit symptomology as a result of spray tank contamination unrelated to a nearby dicamba-tolerant soybean field over which XtendiMax was sprayed. In addition, as applications of dicamba products not registered for use in dicamba-tolerant soybean and cotton continue to increase, dicamba symptomology is increasingly likely to be related to generic dicamba use (discussed in greater detail above, *see supra* pp. 7–9).

- In 2019, Monsanto began collecting quantitative reports of the areas of fields exhibiting various levels of symptomology (slight, moderate, or severe) as a qualitative rating of visual rate response. That information was not collected in 2017 or 2018.

Understandably, we are sensitive to grower and applicator concerns about providing personally identifying information that we have obtained through evaluating inquiries about off-target movement. EPA recognized this important consideration in expressly excluding personally identifiable information from the enhanced reporting requirements in the terms and conditions of the 2018 registration. We have attempted to formulate the information we provide to the agency in a way that respects the growers' and applicators' privacy.

2. Information from litigation involving allegations of adverse effects to non-target plants from dicamba.

As described above, *Bader Farms, Inc. v. Monsanto Co.* was predicated in substantial part on allegations that Monsanto sold dicamba-tolerant seed in 2015–16 before XtendiMax was approved by EPA, which allegedly induced growers to illegally apply other dicamba herbicides that lacked XtendiMax's low volatility and reduced drift potential and ultimately resulted in dicamba-related harm to the plaintiff's peach trees. *See supra* pp. 10–12. As indicated, there was no evidence presented about any particular XtendiMax application on any specific field moving off-target and allegedly impacting the Bader Farms orchards, nor was there any dicamba residue detected at the orchard in the years since XtendiMax was approved for use. On the contrary:

- the only test that ever placed dicamba at Bader Farms was from spring 2015, and that dicamba was confirmed by the plaintiff to have come from an aerial burn-down application unrelated to Xtend crops.[55]

- the FDA's test for dicamba residue in the plaintiff's peaches—the only scientific test conducted for the presence of dicamba in the plaintiff's orchard—found none[56];

- the plaintiff's liability expert, Dr. Ford Baldwin, admitted that he could not determine whether any dicamba that might have reached the plaintiff's orchards

[55] *Bader Farms* Trial Tr. 1045:16–1046:1.
[56] *Id.* at 1085:1–21.

would have been sprayed over dicamba-tolerant crops (as opposed to sprayed over corn, applied for burn-down, or transmitted in some other way)[57]; and

- Dr. Baldwin further admitted to not testing peach tree material from Bader Farms for the presence of dicamba because he was concerned about producing negative results.[58]

In order to provide EPA with a fulsome understanding of the *Bader Farms* litigation, the full trial transcript and all admitted trial exhibits are being transmitted to EPA by a secure file transfer website. Though many of the depositions taken for the case are duplicative of the trial transcript, which was entered into the record via recorded portions of the depositions, a few that provide additional helpful information are included in text or video form, most notably the depositions of Tom Orr, Monsanto's Regulator Affairs Manager, and Ty Witten, Monsanto's North American Crop Protection Lead. Mr. Orr testified regarding Monsanto's pre-registration field studies[59]; the company's validation of its testing methods[60]; the results of testing that show that no adverse effects occur on non-target plants from XtendiMax used according to EPA's label[61]; the confirmatory nature of post-registration testing[62]; and the unreliability inherent in visual symptomology ratings and the need for quantitative data.[63] Dr. Witten testified regarding other causes of visual symptomology that have been discovered in the inquiry process besides dicamba spray or vapor drift sprayed over crops grown from Xtend seeds[64]; the inquiry process not having discovered a single incident of an on-label application of XtendiMax causing adverse effects to non-target plants, as is consistent with the scientific data[65]; the downward trend in inquiries year over year and how the trends compare favorably to other product launches[66]; the benefits of the technology to growers, which include combatting glyphosate-resistant weeds[67]; Monsanto's training efforts to promote on-label application[68]; the need for a field-by-field investigation[69]; and the confirmatory nature of post-registration academic testing.[70] Finally, the expert reports exchanged among Monsanto and the plaintiffs are also provided via secure file transfer website.[71]

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[57] *Id.* at 1410:16–1411:17.
[58] *Id.* at 1356:22–1357:23.
[59] Orr Dep. Tr. 275–88, 290–91, 295–306, 310–19.
[60] *Id.* at 309, 354–55, 358–60.
[61] *Id.* at 322–27, 363–68.
[62] *Id.* 331–32, 333–63.
[63] *Id.* at 280–81, 291–94.
[64] Witten Dep. Tr., 293–94, 418–20, 422.
[65] *Id.* at 298–99, 420–21, 430–31.
[66] *Id.* at 432–36.
[67] *Id.* at 339–41, 353–61.
[68] *Id.* at 389–97, 401–04, 423–24.
[69] *Id.* at 421–22.
[70] *Id.* at 439–45, 459.
[71] This excludes the expert report of Plaintiff's economist, Dr. Joseph Guenthner, which offers no opinions about the off-target movement of dicamba. Monsanto did not want to provide extraneous materials to the volume of litigation materials being provided, but can provide Dr. Guenther's report at EPA's request if it desires a copy.

The transcript also includes the trial testimony of Dr. Baldwin, whose opinions the court allowed because Dr. Baldwin had personally visited the plaintiff's orchards in 2017 and 2018 (though not in 2015 or 2016). Dr. Baldwin's theory was that ubiquitous dicamba uses occurred in the Bootheel region during this time, and that multiple exposures had weakened the plaintiff's peach trees to the point that they succumbed to an opportunistic pathogen. Of course, this county-wide theory runs contrary to the official yield data supplied to EPA previously, demonstrating *record high soybean yields* in the same county during the same years. *See supra* pp. 8–9. Notably, Wayne Mitchem, a weed scientist specializing in peaches, testified that the symptomology on which Dr. Baldwin relied is normal in healthy peach trees.

In addition to the testimonies of the owner of Plaintiff Bader Farms, Monsanto employees, BASF employees, an agricultural economist, an out-of-state tomato farmer whose own crops were not impacted, and a local farmhand who testified that one area grower illegally applied an unapproved dicamba formulation in 2016, the trial testimony includes the expert opinions of two plant pathologists specializing in peach trees. These experts testified that the actual cause of premature tree death in the Plaintiff's orchards was an unrelated tree disease caused by a soil-borne pathogen and that the Plaintiff's peach trees had been dying from this disease long before the commercialization of Xtend seeds. They substantiated their opinions with DNA testing and aerial photos from years prior to 2015 showing the pattern of tree death.[72]

Monsanto has previously informed EPA about the MDL and other pending suits, *see supra* p. 13, but supplies additional information here as well. The index of trial information provided to EPA via a secure file transfer website includes a summary document, listing for each plaintiff the state and county in which the farming operation is headquartered, the crop at issue, and the growing season during which any damage was alleged to have occurred. As indicated above, none of these plaintiffs have provided any evidence indicating that XtendiMax with VaporGrip Technology has resulted in any adverse effects on non-target plants when used according to its label.

As discussed above, each plaintiff, farm, and field involved in the MDL litigation has its own individual circumstances—a point aptly demonstrated by the enclosed expert reports of weed scientists Dr. James Griffin, Dr. Kenneth Savage, who collectively inspected hundreds of the plaintiffs' fields, as well as Dr. Kassim Al-Khatib, who concluded that "in-person field inspections are necessary to accurately diagnose if any exposure to dicamba occurred" and observed a large "variation in the potential causes for symptomology reported by farmers."[73] As indicated, though over 90% of the underlying crop damage claims in the MDL relate to the alleged off-target movement of dicamba onto soybean fields in the 2017 growing season, the court recently excluded most of the plaintiffs' submitted expert opinions because they relied in large part on inferences and generalizations applied to all the plaintiffs as a group, rather than the individual investigations of each field that the court determined are required to identify the cause of any alleged dicamba symptomology.[74] Because, as one of the

[72] *Bader Farms* Trial Tr. 1846:8–1853:20, 1857:2–1903:17, 2148:24–2184:19.
[73] Griffin Rpt. at 2, 3.
[74] *See In re: Dicamba Herbicides Litig.*, ECF #519.

plaintiffs' experts admitted, there are many different factors that can contribute to off-site movement of dicamba, analysis of each field's alleged injuries must be conducted on a case-by-case basis. The court's memorandum and order excluding this expert testimony, as well as the underlying reports, are being provided via a secure file transfer website and an index is also being provided to aid in identifying these documents.

3. Studies and data relating to dicamba off-target movement and toxicity.

The studies detailed above, *supra* pp. 3–7, provide consistent evidence, across a wide range of conditions, supporting EPA's approval of XtendiMax for use on dicamba-resistant soybeans and cotton. Those studies have all been previously provided to EPA, with the exception of the five new studies that confirm the volatility-reducing effects of VaporGrip X when added to XtendiMax as an adjuvant, which Monsanto is providing in a separate, contemporaneous submission. In addition, six of the studies discussed above, initially provided to EPA in October 2018, were provided contemporaneous with EPA's 2018 registration decision (MRID 50717000), so we are noting them here to ensure they are part of EPA's current review of XtendiMax. The reports that were conducted in 2018 and previously submitted to EPA include:

- Field Volatility of Spray Solutions Containing Dicamba for Post-Emergent Uses: MON 76980 (22 oz/A) + MON 79789 (32 oz/A) + Intact (0.5% v/v) – Missouri, MRID 50717001
- Deposition and Air Concentration Modeling for Dicamba Formulation MON 76980 Mixed with MON 79789 and Intact – 2018 Missouri Field Trial, MRID 50717002
- Field Volatility of Spray Solutions Containing Dicamba for Post-Emergent Uses: MON 76980 (22 oz/A) + MON 79789 (32 oz/A) + Intact (0.5% v/v) – Minnesota, MRID 50717003
- Deposition and Air Concentration Modeling for Dicamba Formulation MON 76980 Mixed with MON 79789 and Intact – 2018 Minnesota Field Trial, MRID 50717004
- Field Volatility of Spray Solutions Containing Dicamba for Post-Emergent Uses: MON 76980 (22 oz/A) + MON 79789 (32 oz/A) + Intact (0.5% v/v) – Nebraska, MRID 50717005
- Deposition and Air Concentration Modeling for Dicamba Formulation MON 76980 Mixed with MON 79789 and Intact – 2018 Nebraska Field Trial, MRID 50717006

A summary of six of the academic studies discussed above was also provided at the same time as the above (MRID 50702201) and should also be part of EPA's current review of XtendiMax. Four additional studies conducted in 2018 that were conducted in Illinois and North Dakota were submitted to EPA in April 2019.

- Field Volatility of Spray Solutions Containing Dicamba for Post-Emergent Uses: MON 76980 (22 oz/A) + MON 79789 (32 oz/A) + Intact (0.5% v/v) – Illinois, MRID 50835001
- Deposition and Air concentration Modeling for Dicamba Formulation MON 76980 Mixed with MON 79789 and Intact – 2018 Illinois Filed Trial 1, MRID 50835002
- Field Volatility of Spray Solutions Containing Dicamba for Post-Emergent Uses: MON 76980 (2 oz/A) + MON 79789 (32 oz/A) + Intact (0.5% v/v) – North Dakota, MRID 50835003
- Deposition and Air Concentration Modeling for Dicamba Formulation MON 76980 Mixed with MON 79789 and Intact – 2018 North Dakota Field Trial, MRID 50835004

Monsanto would also be pleased to re-send these or any other studies or data that would be helpful for EPA's review.

Four studies were conducted with tank mix partners that are not currently approved for use with XtendiMax (ammonium sulfate, isopropylamine salt of glyphosate, glufosinate-ammonium). These studies are not consistent with currently approved uses of XtendiMax and are not relevant to the current registration decision. However, these studies are being provided to EPA via the electronic portal as a courtesy:

- Field Volatility of Spray Solutions Containing Dicamba (MON 76980, 119144) for Pre- and Post-emergent Treatments in 2017 Nebraska Field Trial. STC-2017-0417, MSL0029250, MRID 51133703
- Field Volatility of Spray Solutions Containing Dicamba (MON 76980, MON 119151, and MON 76981) for Pre- and Post-emergent Treatments in 2017 Texas Field Trial. STC-2017-0418, MSL0029251, MRID 51133704
- Deposition and Air Concentration Modeling for Dicamba Formulation MON 76890 Mixed with AMS. STC-2017-0418, MSL0030311, MRID 51133705
- Deposition and Air Concentration Modeling for Dicamba Formulation MON 76980 Mixed with Makaze®. STC-2017-0418. MSL0030312, MRID 51133706

Two field studies that were conducted with XtendiMax but not previously reported to EPA are also included. There was significant rainfall shortly after spray application, which caused volatility levels to decrease substantially. Since these conditions likely underestimated potential volatility, they were not previously submitted to EPA but are being submitted to EPA via electronic portal as a courtesy:

- Field Volatility of Spray Solutions Containing Dicamba for Pre-Emergent Uses: MON 76980 (22 oz/A) + MON 79789 (35 oz/A). REG-2016-0288, MSL0028156, MRID 51133701

- Field Volatility of Spray Solutions Containing Dicamba for Post-Emergent Uses: MON 76980 (22 oz/A) + MON 79789 (35 oz/A). REG-2016-0289, MSL0028097, MRID 51133702

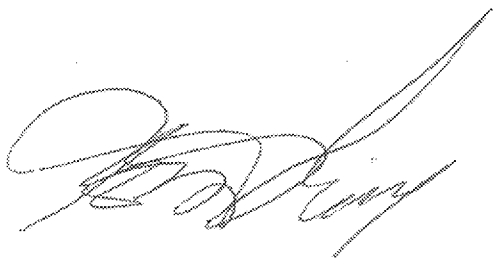
Conclusion

Monsanto is pleased to assist EPA further in evaluating the extensive volume of additional information we supply herewith. We stand ready to explain, discuss, provide relevant context, or otherwise assist in your review of this material. As you know, XtendiMax has been a critical and irreplaceable tool for soybean and cotton farmers in recent years. Growers of millions of acres of soybean and cotton across the United States are relying upon it today as they continue to plant Xtend crops and manage their fields. Please let us know as soon as practicable of any follow-up questions or other issues you would like to discuss.

* * * *

If you have any questions, please contact me at 202-383-2851 or thomas.marvin@bayer.com.

Respectfully submitted,



Thomas Marvin
Head of Regulatory Science North America
Bayer Crop Science
801 Pennsylvania Ave, NW
Suite 745
Washington, DC, 20004